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08.950,963	10.15.1997	JOEL A. DREWES	074022-3302	9997

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ART UNIT	PAPER NUMBER
1631	[REDACTED]

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[Signature]

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No. <b>08/950,963</b>	Applicant(s) <b>Drewes et al.</b>	Examiner <b>Ardin Marschel</b>

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1)  Responsive to communication(s) filed on Jan 18, 2002.

2a)  This action is FINAL.      2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

4)  Claim(s) 1-50 is/are pending in the application.

4a) Of the above, claim(s) 13-17 and 35 is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1-12, 18-34, and 36-50 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims 1-50 are subject to restriction and/or election requirement.

### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11)  The proposed drawing correction filed on Jan 18, 2002 is: a)  approved b)  disapproved.

12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.

2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

- |  |  |
|--|--|
| 15) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                   | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)          | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ | 20) <input type="checkbox"/> Other: _____                                    |

Applicants' arguments, filed 1/18/02, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1, 3, 5, 7-12, 18, and 20-22 are rejected, as discussed below, under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims worded such as claim 1 in the last line the sample flow is indicated as being through "said layers. This confusingly may be interpreted in two ways. It is firstly noted that there are three layers cited in claim 1. Thus, the "said layers" in the last line of claim 1 could reasonably be interpreted as requiring laminar flow through all three layers or alternatively through at least a plurality of layers as also in reasonably interpretable for the phrase "said layers". Clarification of the antecedent basis for the phrase "said layers" in the claims is requested via clearer claim wording. This unclarity is present in independent claims 1, 3, 5, and 18 as well as dependent claims due to their dependence from these independent claims.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 18, 19, and 23 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Brecht et al. [Anal. Chim. Acta. 311:289(1995)].

This rejection is reiterated and maintained from the previous office action, mailed 10/3/01. Applicants argue that the Brecht et al. reference fails to teach laminar flow through or through and across layers of the device. In response it is firstly noted that laminar flow is clearly disclosed on page 292, first column, 4th line under the section entitled "2.3 Setup". The chip layers as recited in the instant claims are constructed as summarized in section 2.2 on page 292, first column. Certain layers are noted as being attached onto the optically functioning layer as a linker layer as well as an active substance layer which bind antibody, such as atrazine. Note that anti-atrazine antibodies are utilized as supplied as noted on page 291, second column, under "2.1 Materials". Such linker and analyte type attachment layers are well known to "not" be flat surfaces such

as a flat piece of glass but rather are made up of molecular moieties of some length which might be visualized during liquid sample practice as blades of grass waving in the current in a lake or river. Thus, the laminar flow liquid procedure as depicted on page 292, Figure 2, clearly includes liquid flow through layers as claimed and thus are still deemed to properly anticipate the above listed instant claims. It is also noted that all of the layers of the device of the reference serve to function in an optical assay and are reasonably deemed optically functioning layers. It is noted that applicants have argued that the optical detection practice of the instant invention does not include fluorescence detection or light scattering citing citations in the instant specification on pages 5, 15, 16, and 20. Consideration of these citations has failed to reveal any negative statement regarding fluorescence or light scattering but rather gives inclusive statements. One specific statement is on page 20, lines 6-10, which clearly defines an optically functional layer only as requiring that a signal be produced via binding of an analyte to a receptive layer or to an attachment layer along with binding of an analyte specific reagent. Thus, fluorescence and scattering type devices are deemed to be included in the practices of the instant invention.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this

## Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 1, 2, 5, 6, 9, 18-20, 22-24, 26, and 36 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Oberhardt (P/N 4,849,340).

This rejection is reiterated and maintained from the previous office action, mailed 10/3/01. Applicants argue that the Oberhardt reference fails to describe optical active layers as instantly claimed. Applicants pointed out that mass change or change in optical thickness is responsible for the detected signal of the instantly claimed optically active layers and not light reflection or fluorescent label presence on the device. In response a variety of optically active layer types are described in the reference as previously pointed to in column 10, line 67,

through column 12, line 29. The detection of bound antigen/antibody conjugates is described in column 30, lines 1-65, wherein in line 65 detection by light scattering is described. Figure 53 is noted in column 29, lines 54-58, as depicting the practice of immobilized or bound antibody for assay usage. The light scattering of said column 30 citation is produced by the antigen/antibody binding of the assay as described which is a mass change thus producing an optical result as also instantly claimed. Also, it is noted that applicants have argued that the optical detection practice of the instant invention does not include fluorescence detection or light scattering citing citations in the instant specification on pages 5, 15, 16, and 20. Consideration of these citations has failed to reveal any negative statement regarding fluorescence or light scattering but rather gives inclusive statements. One specific statement is on page 20, lines 6-10, which clearly defines an optically functional layer only are requiring that a signal be produced via binding of an analyte to a receptive layer or to an attachment layer along with binding of an analyte specific reagent. Thus, fluorescence and scattering type devices are deemed to be included in the practices of the instant invention. It is noted that applicants also argue that solution changes are utilized in the reference for signal generation. This is acknowledged for certain sections of the reference, but the above

newly pointed to immobilized antigen/antibody complex scattering detection practice is not a solution detection method as argued.

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to optionally construct and utilize a device with laminar flow through various layer selections because Oberhardt describes a wide variety of optically active layers as well as supports, channels, analyte attachment layers, etc. as outlined above which are selectable given the various sections directed to these practices in Oberhardt.

Claims 1-7, 18, 19, 21, 23, 25, 36, and 38-43 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Walt et al. (P/N 6,023,540).

Walt et al. summarizes the practice of microsphere based sensing in the title and abstract. Such microspheres are deemed particles as instantly claimed. These microspheres are utilized with bound reagent for analyte detection as depicted, for example, in Figure 3. Figures 5A, 5B, 7A, 7B, 8A-8C, 9A, 9B, 10A, and 10B show these microspheres embedded into sensor surfaces which are also clearly porous. These beads are made of various materials such as plastics, carbon graphite, etc. as summarized in column 5, lines 30-39. It is noted that graphite contains carbon-carbon bonds which are diamond-like albeit without the overall diamond structural strength. Various

detection practices are described in Walt et al. including fluorescent dye detection, Raman scattering, or polarization as noted in column 6, lines 43-52. Scattering is deemed antireflective as required in instant claim 7. It is noted that applicants have argued that the optical detection practice of the instant invention does not include fluorescence detection or light scattering citing citations in the instant specification on pages 5, 15, 16, and 20. Consideration of these citations has failed to reveal any negative statement regarding fluorescence or light scattering but rather gives inclusive statements. One specific statement is on page 20, lines 6-10, which clearly defines an optically functional layer only as requiring that a signal be produced via binding of an analyte to a receptive layer or to an attachment layer along with binding of an analyte specific reagent. Thus, fluorescence and scattering type devices are deemed to be included in the practices of the instant invention. Lastly, many of applicants' claims include a limitation regarding laminar flow. For the purpose of this rejection, it is noted that devices are being claimed and not methods. Thus, the use of a device, that is, with sample laminar flow is not a device limitation per se but a characterization in a product by process type of claim. Such claims are reasonably interpreted as being directed to include the device only, even if utilized in other processes. Also, if there is reason to believe

that laminar flow may be reasonably practiced with the device of the reference while still utilizing the device per se then a rejection based on prior art is proper. Also, if such situations if the reference does not evaluate such a characteristic the burden is shifted to applicants to distinguish the instant invention device per se from the prior art reference. It is acknowledged that laminar flow during sample assay methods is not described in Walt et al. but that samples are generally assayed under reasonably calm conditions such that laminar flow of liquids is expected as a normal type of flow under low flow conditions. Non-laminar flow is generally produced under rapid liquid flow conditions. See the following paragraph for the legal decisions regarding shifting the burden to applicants for distinguishing the instant invention from that of the reference.

It is noted that In re Best (195 USPQ 430) and In re Fitzgerald (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

The non-statutory double patenting rejection, whether of the

obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 5-12, 23, 24, 26-34, and 36-50 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 51, 52, 54, 55, 57-63, 66-68, 70, 71, 73-79, and 82 of copending application Serial No. 09/675,518. Although the conflicting claims are not identical, they are not patentably distinct from each other because the supports claimed in said copending application are not merely supports but also contain layers as instantly claimed. For example, claim 54 of 09/675,518 requires an antireflective layer of diamond-like carbon as well as the support and attachment layer of claim 51 due to its dependence from claim 51. These are embodiments within instant claim 39. Such combinations of limitations are therefore also present in independent claims due to dependent claims therefrom.

It is noted that the particle limitations of certain instant claims, however, are not present in the claims as listed above from the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

May 3, 2002

*Ardin H. Marschel*  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER